AMERICAN NURSES ASSOCIATION

600 MARYLAND AVENUE, SW
SUITE 100 WEST
WASHINGTON, DC 20024-2571
202 651-7000 • FAX 202 651-7001
HTTP://WWW.NURSINGWORLD.ORG

BEVERLY L. MALONE, PHD, RN, FAAN
PRESIDENT

DAVID W. HENNAGE, PHD, MBA
EXECUTIVE DIRECTOR

October 28, 1999

Dockets No. 98N-0313 and 99D-2335
Dockets Management Branch
Division of Management Systems and Policy
Office of Human Resources and Management Services
Food and Drug Administration
5630 Fishers Lange, Room 1061 (HFA-305)
Rockville, MD 20852

Dear FDA Representative:

On behalf of the American Nurses Association (ANA) and the nation's 2.6 million registered nurses, I am submitting comments on:

- FDA Medical Glove Guidance Manual Draft and 21 CFR Parts 801,878, and 880, Surgeon's and Patient Examination Gloves;
- Reclassification and Medical Glove Guidance Manual Availability; Proposed Rule and Notice, data July 30, 1999.

The ANA is the professional association for registered nurses, setting standards for nursing practice, certification and a code of ethics. ANA also promotes the economic and general welfare of registered nurses; in particular, the health and safety of nurses and other health care workers.

ANA appreciates the opportunity to respond to the FDA's request for comments because of our concern for our patients who may be sensitive to natural rubber latex (many of whom are health care workers themselves) and in order to prevent the sensitization of patients and health care workers. In addition, nurses who are sensitized to natural rubber latex need a safe working environment, free from exposure to latex proteins and latex aeroallergens.

According to the National Institute for Occupational Safety and Health. 8-12% of regularly exposed health care workers are sensitized to latex. This is cause for alarm for the 1.3 million

99D-2335

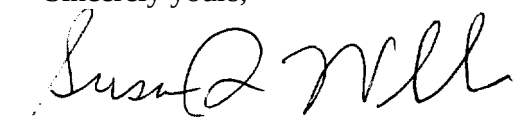
C11

nurses who work in hospitals and are routinely exposed to latex aeroallergens carried by glove powder. There was enough evidence for the American Academy of Allergy, Asthma and Immunology and the American College of Allergy, Asthma and Immunology to jointly recommend the elimination of glove powder in 1997. ANA urges the that the FDA require all surgeon's and patient examination gloves marketed in the U.S. be powder-free.

Because the primary reason that nurse wear medical gloves is to protect from transmision of bloodbome disease, viral barrier integrity is of great importance and the ANA recommends the addition of viral penetration testing to ensure adequate barrier protection.

Thank you for implementing regulations that will reduce the adverse health effects from natural rubber latex allergy caused by protein allergens and glove powder while ensuring quality of medical gloves. If you have any questions or would like further information on these comments, please feel free to contact me.

Sincerely yours,



Susan Q. Wilburn, MPH, RN
Senior Specialist, Occupational Safety and Health

Mailing address:	Susan Wilbum Occupational Safety and Health American Nurses Association 600 Maryland Ave. SW, Suite 100 West Washington, D.C. 10024-2571
Phone:	(202) 651-7130
Email:	swilbum@ana.org

cc: David W. Hennage, PhD, MPH, Executive Director
Beverly L. Malone, PhD, RN, FAAN, President

General Comments and Timeline

The ANA applauds the FDA for it's efforts to prevent the sensitization of nurses and other health care workers to natural rubber latex protein and strongly supports improved labeling requirements for gloves that will provide health care professional consumers of medical gloves with important information needed to make good glove choices. The proposed regulations will assist health care professionals, patients and lay users to select a lower risk device by providing information about protein and glove powder levels. This choice should not, however, expose others to undue risk. According to the FDA, five health care workers deaths related to natural rubber latex medical glove use have been reported (four of them nurses).

The 1997 ANA Position Statement (attached to these comments) calls for the use of gloves with adequate barrier protection to prevent exposure to bloodbome pathogens and only powder-free, low-protein natural rubber latex gloves, where latex is used.

ANA recommends:

- FDA should require all surgeon's and patient examination gloves marketed in the U.S. be powder-free and limit the amount of protein to 600 micrograms per glove.

- FDA should implement chemotherapy labeling and viral barrier testing.

ANA is very concerned about the urgent need to provide a safe environment for the care of latex allergic patients and health care workers. ANA prefers a l-year effective date, but also shares the FDA's concern about a potential glove shortage. Therefore, ANA recommends the implementation of the labeling requirements for protein and powder within one year and elimination of powdered latex gloves within 2 years.

Glove Powder (including air handling)

Glove powder is a significant source of circulating latex proteins in the air triggering pulmonary reactions in latex allergic patients and workers. The American Academy of Asthma, Allergy and Immunology along with the American College of Asthma, Allergy and Immunology determined that enough evidence existed to call for the elimination of glove powder in 1997. The FDA's 1997 Glove Report and the Proposed Rule being considered provide additional background regarding the increased risk of surgical wound infections and adhesions from glove powder.

The FDA should not recommend the use of special air handling systems for those facilities using powdered surgeon's and patient examination gloves with powder levels over 120mg per glove. regardless of glove size. ANA believes that the FDA should institute a requirement to market only powder-free gloves in the United States. The goal of eliminating latex aeroallergens is best served by eliminating powdered latex gloves at the source. Special air handling does not address

the root cause of the problem and will require the purchase and maintenance of equipment, standards for cleaning of filters, and standards for allowable airborne protein and powder levels. ANA believes that efforts are more cost effective and better focused at the source of the allergen.

ANA appreciates the desirability of ease in donning gloves, but believes that the health effects outweigh the need for donning powder. In addition, glove coatings are available to ease donning of gloves.

Chlorination Alternatives

ANA is concerned about the use of chlorination to remove powder because of the impact of chlorination on the glove barrier and the toxicity of residual chlorine on gloves. ANA urges the FDA to explore alternatives to the use of chlorine for removal of powder.

Latex Protein Levels

The ANA is unaware of any study that indicates that 1,200 micrograms of protein per glove is safe to prevent sensitization and is aware that no level of latex protein exposure is safe for an individual with a Type I IgE latex hypersensitivity.

FDA should require no more than twice the level measurable - 600 micrograms of protein per glove in the 6 gram, 300 microgram glove used as an example in the proposed rules.

Viral Barrier Integrity

The primary purpose for wearing medical glove is to prevent exposure to bloodborne disease. The FDA should require all gloves marketed and sold for medical use to pass a viral penetration test and include in-use testing of gloves.

Labeling

Gloves that are marketed for use with chemotherapy drugs should be tested and labeled for the "breakthrough detection time" as per the ASTM F739, "Standard Test Method for Resistance of Protective Clothing Materials to Permeation by Liquids or Gases Under Condition of Continuous Contact".

Promising research has been conducted on the strength, flexibility and durability of synthetic alternative to latex gloves, such as nitrile, but most of the research has been conducted by manufacturers. The FDA should promote research on alternatives to natural rubber latex gloves especially the effectiveness of the barrier.

AMERICAN NURSES ASSOCIATION

Position Statement
on

Latex Allergy

SUMMARY: Natural rubber latex allergy is a serious medical problem for a growing number of patients and a disabling occupational disease among health care workers. Latex allergy develops from exposure to natural rubber latex, a plant cytosol that is used extensively to manufacture medical gloves, other medical devices, and numerous consumer products. Allergic reactions to latex range from skin disease to asthma and anaphylaxis that can result in chronic illness, disability, career loss, hardship, and death. There is no treatment for latex allergy except complete avoidance of latex. Patients and health care providers must be assured safety from iatrogenic sensitization and allergic reactions to latex. Therefore, the American Nurses Association supports immediate interventions to reduce the risk of latex sensitization and ensure safe outcomes for latex-sensitized patients and personnel in all health care settings. Successful interventions will require collaboration between health care providers and administrators, with support from the research community, government agencies, manufacturers, professional organizations, sensitized patients, and patient advocacy groups.

BACKGROUND

Delayed contact dermatitis from chemicals in rubber has been recognized since the 1930s.[4] 'But except for rare early reports, clinicians did not appreciate systemic allergic reactions to latex proteins until 1979, when case reports began to appear in Europe.' Latex allergy erupted in the United States shortly after the Centers for Disease Control introduced universal precautions in 1987. By late 1992, the Food and Drug Administration (FDA) received 1133 reports of serious allergic reactions and anaphylaxis occurring to patients and health care staff associated with 30 classes of latex medical devices. There were 15 patient deaths associated with latex barium enema catheters.[5,6] The FDA estimated that the reports represented only 1% of actual occurrences.[6] Today, researchers hypothesize that the latex allergy outbreak is the result of multiple factors including deficiencies in manufacturing processes, increased latex exposure, hand care practices, immunological cross reactivity, and changes in latex agricultural practices. [1,7,8, 45]

Latex allergy affects between 8%-12% of workers in all health disciplines.[43] Latex allergy also affects up to 51% of children with spina bifida, and approximately 1% of the general population.[45]

Definitions

Two types of allergies are associated with rubber: a) chemical contact dermatitis, and b) latex protein immediate hypersensitivity, which is termed latex allergy.

American Nurses Association
600 Maryland Avenue, SW
Washington, D.C. 10024

Chemical contact dermatitis is a delayed cell-mediated Type IV localized allergy that is caused by chemicals used to manufacture rubber products. The most common contact sensitizers are the accelerators: thiurams, mercaptobenzothiazols (MBTs), and carbamates. [1]

Latex allergy is a Type 1 IgE-mediated hypersensitivity reaction that involves systemic antibody formation to proteins in products made from natural rubber latex. Natural rubber latex is harvested commercially from the rubber tree, ***Hevea brasiliensis***, and used to manufacture rubber products. Natural rubber latex contains up to 240 potentially allergenic protein fragments, and different persons may be sensitized to different combinations of latex allergens.* Synthetic latexes (e.g. synthetic latex paint or synthetic rubber) are not involved in latex allergy; therefore, this document refers only to natural rubber latex, henceforth termed latex.

Contact dermatitis, including both irritant and allergic responses, is the most common clinical reaction associated with the use of latex gloves, Irritant contact dermatitis is not an allergy.

Physiologic Effects, Diagnosis and Treatment

Latex exposure occurs through contact with the skin or mucous membrane, and by inhalation, ingestion, parenteral injection or wound inoculation. Data on the dose and duration of exposure, and the specific proteins required to produce sensitization are incomplete. Risk factors include occupational exposure to latex, multiple surgical procedures or mucosal instrumentation involving latex, and a personal or family history of allergies. Other unrecognized risk factors may exist.[16]

Latex sensitization causes skin disease, urticaria, angioedema, rhinoconjunctivitis, sinusitis, asthma, gastrointestinal symptoms, anaphylaxis and death.[8,19] Symptoms may present gradually and progress, although some individuals skip this progression and experience an abrupt onset of anaphylaxis or asthma. [19] Highly sensitized individuals can react to minute latex exposures.[7,19] Sensitized persons also may develop immunologic cross-reactivity with fruits and vegetables that may have molecular structures analogous to latex, such as avocado, banana, European chestnut, the drupes (e.g., almond, cherry, peach, nectarine, etc.), kiwi, papaya, tomato, potato and others.[7,19,20]

There is no treatment for latex allergy except complete avoidance of latex, although eventually immunotherapy may become available.[12,21] Early diagnosis and latex avoidance are essential because continued exposure can lead to advanced allergic symptoms that disrupt careers and everyday living, and create serious barriers to health care.[19] Latex-sensitized persons should take the following precautions: a) avoid all contact with latex, b) carry auto-injectable epinephrine, and consult physicians for alternatives to beta blockers that are prescribed for other conditions, c) wear a medical identification bracelet, and d) negotiate with hospitals and providers in advance for latex-safe health and dental care. In turn, providers must be prepared to identify sensitized patients and deliver all levels of patient care, including emergency treatment, using nonlatex medical devices in an environment that is free of latex contamination.[19,22,23]

Medical Glove Allergenicity and Safe Use **Practices**

Latex medical gloves are the most prominent source of latex allergen exposure by cutaneous

contact, inhalation, wound inoculation and ingestion.[27,48] Allergens levels vary considerably in gloves from different manufacturers, and from lot to lot, with higher levels occurring in powdered gloves and examination gloves than in powder-free gloves and surgical gloves.[24,27] Latex gloves that are inadequately processed during manufacture contain loosely-bound protein that readily rubs off or leaches into sweat, then accumulates on glove wearers' hands and easily transfers by touch to other persons and objects (e.g. medical records, telephones, doorknobs, food, etc.).** Therefore, it is essential that glove users wash their hands between glove changes and after removal, and avoid touching objects or latex-sensitized persons with latex gloves or unwashed hands.[4,28] Glove powder is a strategic factor in allergen exposure. Cornstarch donning powder actively extracts and binds protein from latex, which accumulates on glove wearers' hands, transfers onto objects, and aerosolizes.[28] Airborne particles of powder and protein may remain suspended for up to 5 hours, contaminating the air, ventilation system, skin, hair, clothing, wounds, and objects which can result in occupational asthma.[29,46] Therefore, health care providers must never use latex gloves in the care of latex-sensitized patients and must not use powdered latex gloves in general.[4,21,30,46,47] Low allergen, powder-free gloves decrease allergen exposure,[4,28,29,31,32] and also reduce the incidence of allergic reactions and occupational asthma among sensitized workers.[4,21,33,34]

Glove-Associated Hand Dermatitis

Hand dermatitis, which is endemic among glove users, frequently is associated with occupational latex allergy.[35,36] Skin damage caused by dryness, irritation, contact dermatitis, or other dermatoses not only increases the risk of exposure to pathogens, but also may enhance absorption of glove chemicals and latex protein allergens.' Hand dermatitis may be a manifestation of either chemical contact dermatitis or latex allergy," or co-existent contact dermatitis and latex allergy.[36] Therefore, glove wearers who develop hand dermatitis should seek early medical differential diagnosis that includes patch testing for glove chemical allergy, and latex allergy testing.[36,37] Although glove wearers with dermatitis commonly believe they are allergic to glove powder, sensitization to glove powder has never been shown conclusively.[37] Therefore, symptomatic persons should not delay in seeking differential diagnoses from physicians who are knowledgeable about glove-related allergies.

Glove wearers who use oil-based hand care products or medications to treat skin conditions increase their risk of exposure to allergens and microorganisms. Oil-based ingredients (e.g., jojoba, aloe vera, palm oil, coconut oil, lanolin, mineral oil, petrolatum products) degrade the molecular structure of latex and some synthetic glove materials within a few minutes, releasing protein and chemicals, and facilitating the passage of microorganisms.[4,38] Alternatively, water or glycerin-based hand care products are compatible with latex. Soaps, detergents, alcohol and various chemicals also degrade latex. Therefore, latex medical gloves are inappropriate for hospital housekeeping because they increase staff exposure to microorganisms and allergens,[39] and can contaminate the environment with allergens. Similarly, latex medical gloves are inappropriate for food service workers because they produce unnecessary risk for hand dermatitis and latex allergy, and may contaminate food with latex proteins, resulting in allergic reactions in sensitized persons.[40]

Glove Selection

Once a diagnosis of contact dermatitis or latex allergy is established, empioyers must provide

gloves that are free of the causative agent.[41] Workers who have chemical contact dermatitis require gloves that have been sufficiently processed to remove the sensitizing chemical, and latex-sensitized persons must never wear latex gloves.[4,19,21,42] The "hypoallergenic" label generally means that gloves are low in chemical contact sensitizers, but "hypoallergenic", does not refer to latex allergens in gloves. [1]

RECOMMENDATIONS

Therefore, the American Nurses Association recommends the following actions to protect patients and personnel from latex allergy in all health care settings:

1. Based on current research, all health care institutions should eliminate the unnecessary use of latex gloves and implement the use of low-allergen, powder-free latex gloves in all other settings.[3,46,47]

2. Each facility shall convene a multi-disciplinary latex allergy task force to develop ***patient care*** guidelines to:

   a) ensure that the environment is free of contamination by latex and other substances carried by glove powder;
   b) identify latex-sensitized patients and those at risk, instruct them about self-care, and deliver latex-safe care in accordance with recommended practice guidelines;
   c) establish an inventory of nonlatex alternatives for latex medical devices;
   d) develop procedures to identify and resolve problems with medical devices relevant to allergic reactions or glove performance;
   e) report allergic events related to latex medical devices to the Food and Drug Administration MedWatch Program (phone 1-800-FDA-1088, Fax 1-800-FDA-0178).

3. Each health facility shall develop multi-disciplinary latex allergy *occupational health* guidelines that will:

   a) ensure a workplace that is free of contamination by latex and other substances carried by glove powder;
   b) educate personnel regarding latex allergy and related issues of hand care, hand dermatoses, glove use, product problem reports, and continued adherence to universal precautions;
   c) provide task-appropriate, powder-free, low allergen gloves, and enlist manufacturers' support to resolve glove-related problems;
   d) facilitate early identification, diagnosis, treatment and tracking of personnel with hand dermatoses or symptoms of latex allergy;
   e) report allergic events related to latex medical devices to the Food and Drug Administration MedWatch Program (phone 1-800-FDA-1088, Fax 1-800-FDA-0178);
   f) accommodate latex-sensitized employees safely in the workplace, assist disabled employees to obtain rehabilitation services, and direct disabled personnel to

compensatory benefits when rehabilitation is not possible.

4. All health personnel shall:

a) be knowledgeable of latex allergy and its related issues;
b) implement latex allergy guidelines pertaining to the safety of patients and staff;
c) seek occupational health services and medical care for early diagnosis and treatment of hand dermatoses and symptoms suggestive of latex allergy and request documentation of glove-associated illness to OSHA;
d) report allergic events related to latex medical devices to the Food and Drug Administration MedWatch Program (phone 1-800-FDA-1088, Fax 1-800-FDA-0178);
e) be knowledgeable about employees' rights to workplace safety, reasonable accommodations for latex-sensitized personnel to remain employed, rehabilitation services, and compensatory benefits for disability when rehabilitation is not possible.

Effective Date:	September 15, 1997
Status:	Position Statement
Originated by:	Congress on Nursing Economics
Adopted by:	ANA Board of Directors
Related Past Actions:	1995 - Hazardous Workplace Air Quality 1994 - Risk Versus Responsibility in Providing Nursing Care 1993 - Health and Safety in the Workplace 1984 - Employees Right to Know Hazards in the Workplace 1982 - Health Hazards in the Workplace

FOOTNOTES

1. Truscott, W. (1995). The industry perspective on latex. *Immunology and Allergy Clinics of North America, 15*(1), 89-121.
2. Alenius, H., Kurup, V., Kelly, K., Palosuo, T., Turjanmaa, K. & Fink, J. (1994). Latex allergy: Frequent occurrence of IgE antibodies to a cluster of 11 latex proteins in patients with spina bifida and histories of anaphylaxis, *Journal of Laboratory and Clinical Medicine, 123,* 712-720.
3. Kelly, K.J., Sussman, G., & Fink, J.N. (1996). Stop the Sensitization. *Journal of Allergy and Clinical Immunology, 98, 857-859.*
4. Truscott, W. & Roley, L. (1995). Glove-associated reactions: Addressing an increasing concern. *Dermatology Nursing, 7*(5), *283-292.*
5. Granady, L.C. & Slater, J.E. (1995). The history and diagnosis of latex allergy. *Immunology and Allergy Clinics of North America, 15*(1), 21-29.
6. Levy, D.A. (1993). Report on the International Latex Conference: Sensitivity to Latex in Medical Devices, Baltimore, MD, USA 5-7 November, 1992. *Allergy, 48*(4, Suppl.) l-9.
7. Charous, B.L. (1994). The puzzle of latex allergy: Some answers, still more questions. Annals *of Allergy, 73*(4), *277-28* 1.
8. Hamann, C.P. (1993). Natural rubber latex protein sensitivity *in* review. ***American Journal of***

Contact Dermatitis, 4(1), 4-2 1.
9. Food and Drug Administration, Center for Devices and Radiological Health. (1993). ***Regulatory requirements for medical gloves: A workshop manual*** (HHS Publication No. FDA 93-4257). Rockville, MD: Center for Devices and Radiological Health.
10. Food and Drug Administration, Center for Devices and Radiological Health. (1992) ***Program and proceedings: International Latex Conference: Sensitivity to Latex in Medical Devices.*** Rockville, MD: Center for Devices and Radiological Health.
11. Food and Drug Administration and Health Industry Manufacturers Association. (undated). ***Gloves: Information about medical gloves.*** Rockville, MD: Food and Drug Administration, Center for Devices and Radiological Health.
12. American College of Allergy, Asthma and Immunology. (1995). Latex allergy - an emerging health ***care problem. Annals of Allergy, Asthma & Zmmunology,*** 75(1), 19-21.
13. Food and Drug Administration, Center for Devices and Radiological Health. (1995, March ***9). Interim guidanceforo protein content labeling claim for latex medical*** gloves (letter). Rockville, MD: Center for Devices and Radiological Health.
14. Food and Drug Administration, Center for Devices and Radiological Health. (1995). ***To medical*** glove ***manufacturers*** (letter). Rockville, MD. Food and Drug Administration, Center for Devices and Radiological Health.
15. Food and Drug Administration. (1995, March 24). ***Latex allergy test clearedfor marketing*** (FDA Talk Paper). Rockville, MD: Food and Drug Administration Press Office.
16. Kelly, K.J., Kurup, V.P., Reijula, K.E. & Fink, J.N. (1994). The diagnosis of natural rubber latex allergy. ***Journal of Allergy and Clinical Zmmunology, 93***(5), 813-816.
17. Ownby, D.R., Ownby, H.E., McCullough, J.A., & Shafer, A.W. (1994). The prevalence of anti-latex IgE antibodies in 1000 volunteer blood donors. ***Journal of Allergy and Clinical Immunology, 93***(1, Pt. 2), 282. (Abstract No. 717).
18. Thompson, R.L. (1995, November 16) Educational ***challenges of latex allergy.*** Paper presented at Latex Allergy: A One Day Seminar, Chicago.
19. Kelly, K.J. (1995). Management of the latex-allergic patient. ***Zmmunology and Allergy Clinics of North America, 15***(1), 139-157.
20. Beezhold, D.H., Sussman, G.L., Liss, G.M. & Chang, N.S. (1996). Latex allergy can induce reactions to specific foods. ***Clinical and Experimental Allergy, 26***(5), 416422.
21. Slater, J.E. (1994). ***Latex*** allergy, ***Journal of Allergy and Clinical Zmmunology, 94 (2,*** Pt. 1), 139-50.
22. American Academy of Allergy & Immunology. (1993). Task Force on Allergic Reactions to ***Latex:*** Committee Report. ***Journal of Allergy and Clinical Zmmunology, 92***(1, Pt. 1), 16-18.
23. American College of Allergy & Immunology, Task Force on Latex Hypersensitivity. (1992). Interim recommendations to health professionals & organizations regarding latex allergy precautions. Palatine, IL: American College of Allergy & Immunology.
24. Jones, R.T., Scheppmann, D.L., Heilman, D.K. & Yunginger, J. W. (1994). Prospective study of extractable latex allergen contents of disposable medical gloves. ***Annals of Allergy,*** *73*(4), 321-325.
25. Wrangsjo, K.& Lundberg, M. (1996). Prevention of latex allergy. ***Allergy, 51***(1), 65-67.
26. Alenius, H., Makinen-Kiljunen, S., Turjanmaa, K., Palosuo, T. & Reunala, T. (1994). Allergen and protein content of latex gloves. *Annals of Allergy*, *73*(4), 315-320.
27. Yunginger, J.W. (1995). Variances in antigenicity of latex products. ***Immunology and Allergy Clinics of North America, 15***(1), 61-70.
28. Beezhold, D.H., Kostyal, D.A. & Wiseman, J. (1994). The transfer of protein allergens from latex gloves: A study of influencing factors. *AORN Journal, 59*(3), pp. 605, 607-608, 610,

612-613.
29. Swanson, M.C., Bubak, M.E., Hunt, L.W., Yunginger, J.W., Warner, M.A. & Reed, C.E. (1994). Quantification of occupational latex aeroallergens in a medical center. ***Journal of Allergy and Clinical Immunology, 94, (3,*** Pt. 1), 445-45 1.
30. Kelly, K. (1993). Management of the latex-allergic patient. *Immunology and Allergy Clinics of North America, 15*(1), 139-157.
31. Siu, S.R., Smith, G.J., Sussman, G.L., Swanson, M.C., Yunginger, J., Cividino, M.P., Brown, S.A. & Beezhold, D. (1996). Reduction in airborne latex protein exposure by use of low protein, powder-free gloves. ***Journal of Allergy and Clinical Immunology,*** *97*(1, Pt. 3), 325. (Abstract No. 569).
32. Abbosh, J., Ownby, D. & McCullough, J. (1996). Quantitation of airborne latex allergens produced by bursting and snapping latex gloves. ***Journal of Allergy and Clinical Immunology,*** *97*(1, Pt. 3), 429. (Abstract No. 985).
33. Tarlo, S.M., Sussman, G., Contala, A. & Swanson, M.C. (1994). Control of airborne latex by use of powder-free latex gloves. ***Journal of Allergy and Clinical Immunology, 93***(6), ***985-989.***
34. Sussman, G.L., Pugh, B. & Beezhold, D.H. (1996). Latex allergen levels in disposable medical gloves. ***Journal of Allergy and Clinical*** Immunology, *97*(1, Pt 3), 326. (Abstract No. 573).
35. Charous, B.L., Hamilton, R.G. & Yunginger, J.W. (1994). Occupational latex exposure: Characteristics of contact and systemic reactions in 47 workers, ***Journal of Allergy and Clinical Immunology, 94*** (1), 12-18.
36. Taylor, J.S., & Praditsuwan, P. (1996). Latex allergy: Review of 44 cases including outcome and frequent association ***with*** allergic hand eczema. ***Archives of Dermatology, 132***(3), 265-271.
37. Turjanmaa K. (1994). Contact urticaria from latex gloves. In G.A. Mellstrom, J.E. Wahlberg, & H.I. Maibach (Eds.), ***Protective gloves for occupational use*** (pp. 241-254). Boca Raton, FL: CRC Press.
38. Truscott, W. (1995). They're not just gloves: A guideline on proper use. ***Chicago Dental Society Review, 88***(2), ***22-29.***
39. Sussman, G.L., Lem, D., Liss, G. & Beezhold, D. (1995). Latex allergy in housekeeping personnel. ***Annals of Allergy, Asthma & Zmmunology, 74***(5), 415-418.
40. Schwartz, H.J. (1995). Latex: A potential hidden "food" allergen in fast food restaurants. ***Journal of Allergy and Clinical Immunology, 95***(1, Pt. 1), 139-140.
41. Occupational Safety and Health Administration. (1991, December 6). 29 CFR part 1910.1030. Occupational Exposure to Bloodbome Pathogens; Final Rule. ***Federal Register, 56***(235), 6417564182.
42. Gehring, L.L., Fink, J.N. & Kelly, K.J. (1996). Evaluation of low allergenic latex gloves in latex sensitive patients. ***Journal of Allergy and Clinical Immunology, 97***(1 Pt. 3), 186. (Abstract No. 13).
43. Komiewicz, D. (1996). Barrier protection of latex. ***Immunology and Allergy Clinics of Nonh America, 15***(1), 123-137.
44. Turjanmaa, K., Alenius, H., Makinen-Kiljunen, S., Reunala, T., & Palosuo, T. (1996). Natural rubber latex allergy. ***Allergy 5*** 1, 593-602.
45. Slater, J.E. (1992). Allergic reactions to natural rubber. ***Annals of Allergy,*** *68*(3), 203-209.
46. American Academy of Allergy, Asthma, and Immunology (AAAAI) and American College of Allergy, Asthma, and Immunology (ACAAI) ***Joint Statement Concerning the Use of Powdered and Non-Powdered Natural Rubber Latex*** Gloves. Arlington Heights. IL: ACAAI,

July 21, 1997.
47. Department of Health and Human Services (DHHS) National Institute for Occupational Safety and Health (NIOSH). ***NIOSH Alert: Preventing Allergic Reactions to Natural Rubber Latex in the Workplace*** [DHHS (NIOSH) Publication No. 97-135], 1997.
48. Yunginger, J., Jones, R., Fransway, A. et al. (1994). Extractable latex allergens and proteins in disposable medical gloves and other rubber products. ***Journal of Allergy and Clinical Immunology, 93: 83-42.***

G:\position\workplac\latexall.97
10/27/97

HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

CROSS REFERENCE SHEET

Docket Number/Item Code: 99D-2335/C11

See Docket Number/Item Code: 98N-0313/C37